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SIPDIS

DEPARTMENT FOR EAP/ANP-TRAMSEY, EB/TPP/MTA/IPC-PACETO AND
EB/TPP/BTA/ANA-RARMSTRONG
STATE PASS TO USTR FOR BWEISEL
COMMERCE FOR 4530/ITA/MAC/AP/OSAO/GPAINE
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SENSITIVE

E.O. 12356: N/A
TAGS: KIPR ECON ETRD NZ
SUBJECT: REVISED PATENT LAW WON'T HELP DRUG INDUSTRY IN
NEW ZEALAND

¶1. (U) Summary: A proposed revision of New Zealand's patent law will disappoint pharmaceutical companies by failing to extend the effective patent life of drugs -- stuck at seven years on average -- and prohibiting patents for methods of medical treatment. U.S. pharmaceutical firms especially wanted a longer patent term, which would increase the time they could profit from their inventions before they faced competition from generics.

¶2. (SBU) U.S. pharmaceutical firm representatives we spoke with suspect the New Zealand government is not extending the patent term in order to retain a card to play in possible free-trade negotiations with the United States. But, the decision also is consistent with the government's efforts to hold down drug prices. Policies supporting that objective already have caused some pharmaceutical firms to leave the New Zealand market and others to reduce their profile and investments in the country. The proposed patent amendment will help sustain that trend. End summary.

Joining the 21st century

¶3. (U) Following Cabinet's instructions, the Ministry of Economic Development is drafting legislation to revise the Patents Act ¶1953. The ministry hopes to publicly release the draft before the end of the year, with the legislation to be introduced in Parliament in early 2005, according to a ministry official.

¶4. (U) The revision is intended to bring New Zealand's patent law into closer conformity with international standards. New Zealand is one of the few countries that apply a "local novelty standard" for granting a patent. As the patent law now stands, an invention is considered new and therefore patentable if no earlier publication or use had occurred in New Zealand before the filing of the patent application. The revision would make patents more difficult to obtain by requiring the invention not only to be new -- anywhere in the world -- but also to involve an inventive step, the ministry official said. Taking into account technological and social changes since 1953, the amended law would place New Zealand in harmony with its major trading partners, Australia and the United States, in determining patentability. The result is that overseas investors and companies should face fewer barriers to commercial development of their inventions. About 90 percent of New Zealand patents are granted to overseas intellectual property owners.

¶5. (U) A review of the Patents Act was initiated in 1989, but was put on hold in 1990 due to the indigenous Maoris' concerns for protecting their cultural heritage, according to the ministry official. The review was reopened in 2000. The resulting proposed revisions would establish a Maori consultative committee to advise the patents commissioner on whether an invention involves traditional knowledge or indigenous plants and animals or is contrary to Maori values. Patent protection could be denied if commercial exploitation would be contrary to morality or public order, to protect human or animal or plant, or to avoid serious harm to the environment. These provisions could be applied to genetic material, although such material is not specifically excluded from patentability. The ministry official said the exclusions would be allowed under Article 27(2) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

No patents for methods of treatment

¶6. (U) The proposed amendment also will exclude from patentability human beings and methods of treating them. Publicly, the government has cited ethical reasons for the exclusions, contending that it would be immoral to constrain for commercial reasons a doctor's ability to use the best available methods to treat patients. Privately, the ministry official told us a primary concern was that patents covering medical methods could increase public health costs. He said the government was not convinced that the benefits of such patents would outweigh their costs.

¶7. (U) The methods-of-treatment exclusion is the government's

response to court decisions saying that the legislature -- not the judiciary -- had to decide whether such methods could be patented. In the most recent case, the New Zealand Court of Appeal ruled June 28 against Pfizer by holding that the Patents Act 1953 did not cover methods of treating humans. Such methods thus were not patentable, nor could the court find a basis for broadening the act's scope, as it had been asked to do by Pfizer's attorneys.

¶8. (U) Pfizer had filed two patent applications in 1998 for methods of treating psychotic disorders using a new compound. Turned down by the patents office, the company took the case to court. Pfizer had offered to the Court of Appeal to include a disclaimer relinquishing its right to sue doctors, who otherwise might face a decision to withhold treatment or risk being sued for breach of patent. The court said the disclaimer was inadequate.

¶9. (U) Pfizer has been joined by other drug companies in contending that the exclusion of methods of treatment from patent protection could further hinder medical research and development in New Zealand. With less profit incentive to research alternative uses of existing drugs, pharmaceutical companies may forgo the pursuit of other applications in New Zealand.

No change in patent term

¶10. (U) The revised law also would keep the maximum patent term in New Zealand at 20 years, as established by legislation enacted in 1994. That law, which also abolished patent extensions, brought New Zealand into line with its TRIPS agreement obligations. However, of all OECD countries, only New Zealand and Canada do not provide for patent extensions. Because the time required to review patent applications is included in the 20-year term, the pharmaceutical industry contends that the effective patent life of drugs in New Zealand is about seven years.

¶11. (U) The industry also points to another provision in New Zealand law that shortens the time that a company can benefit from exclusive rights to pharmaceutical products. A December 2002 amendment to the Patents Act allows generic competitors to engage in "springboarding," or to prepare their product for market while a proprietary drug is still under patent. This provision has allowed generic products to enter the market on the heels of a patent's expiration. No change is expected under the revised patents law.

¶12. (U) The Cabinet decided in December 2002 to include the issue of patent term extension for pharmaceuticals in the Patents Act review. However, in mid-2004, Cabinet -- without explanation -- dropped the issue from an economic study of the Patents Act. The official from the Ministry of Economic Development told us the new patents bill would not address the issue.

¶13. (SBU) Although officials have declined to comment on why the Cabinet nixed a patent extension for pharmaceuticals, some in the industry have suspicions. Representatives from two U.S. pharmaceutical companies in August separately told the Consul General in Auckland that there was strong speculation, backed by their discussions with high-level government staff, that the study of pharmaceuticals' patent life had been sidetracked to give New Zealand "something to trade away" when, or if, New Zealand was asked to enter free-trade negotiations with the United States. As it now stands, New Zealand will not even undertake an analysis of the possible benefits of an extended patent term for drugs, the drug company representatives complained.

¶14. (U) The pharmaceutical industry group, Researched Medicines Industry Association (RMI), asserts that adequate intellectual property protection is critically important to nurture researched-based industries in New Zealand. Lesley Clarke, RMI's chief executive officer, said the length of the patent term is an important factor weighed by pharmaceutical multinationals in deciding where to invest in research and site their laboratories.

Comment

¶15. (U) Cost control has long been a primary aim of the New Zealand government's approach to providing health care to its citizens. As a result, New Zealand ranks 20th of the 30 OECD countries in terms of per-capita spending on health. It has managed to control medical costs in large part by restricting access by its doctors and their patients to newly introduced pharmaceuticals and cutting-edge medical treatments. Access has been limited by slowing the inclusion of new and expensive pharmaceuticals to a tightly controlled list of approved drugs for which the government subsidizes costs. The net effect to drug companies is to hamper their ability to profit from their inventions. The government's decisions not to extend patent life or allow patents on medical treatment give the industry yet another reason to reduce its stake in the country.

¶16. (SBU) Meanwhile, the government has identified the biotechnology industry as a critical component of its plan for

long-term, sustainable economic growth. At some point, it seems likely that the government will need to resolve the often conflicting objectives of its tight-fisted controls on medical practice and its encouragement of a biotechnology industry. Until that day arrives, the two goals will share an uneasy co-existence.

SWINDELLS